PHARMALEX

Stab·e·lity

Stab·e·lity Version 3.0

SECURITY & CONFIDENTIALITY FORM

Stab.e.lity is a software application that manages the evaluation of stability data acquired from new drug substances and generates the associated information in compliance with international guidelines for both biological and non-biological products.

Stab.e.lity is a product of:

PharmaLex Belgium.

Avenue Edouard Belin, 5 – 1435 Mont-Saint-Guibert

Belgium

This product was managed by *PharmaLex Belgium.*

As a supplement to the *STAB3.0-18.V03 Factory Release form*, PharmaLex Belgium guarantees the security and the confidentiality of data submitted to *Stab.e.lity* due to the fact that:

- In order to connect to the *Stab.e.lity* application, users need a personal login and a password which must be changed every 60 days.

- Upon log-off, all submitted data are deleted from the server. Moreover, the generated reports that have been created by the user are neither saved nor stored on the server. In the case of non-activity for a period exceeding 30 minutes, an automatic log-off is carried out.

- The transfer of all data is protected and encrypted by an *SSL Certificate* with a *256-bit (AES-256) key*.

- The production Server is hosted at *CEGEKA N.V, Universiteitslaan 9 (B-3500), Hasselt, Belgium* *Cegeka* is a company specializing in the provision of the requirements necessary for the secure hosting of such an application, contracted on *June 13th 2003*.

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System Owner	*Project Leader*	*Quality Assurance Manager*
(PharmaLex Belgium)	*(PharmaLex Belgium)*	*(PharmaLex Belgium)*
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V02: change of Head offices address & replacement of CEO by Project Leader / Head of Programming

V03: Change Company name and logo, project leader name and replacement of Qa associate by the System Owner.